DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 25, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-64

Richard S. Kee, Owner
Kee's Company
5619 Matin Luther King Jr. Way South
Seattle, Washington 98118

WARNING LETTER

Dear Mr. Kee:

We inspected your firm located at 5619 Martin Luther King Jr. Way South, Seattle, Washington, on June 5, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. A FDA 483 form (copies enclosed) listing the deviations was presented to you at the conclusion of the inspection on June 5, 2000. These deviations cause your sprouts to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act through links in FDA's homepage at www.fda.gov.

Your firm's sprouts are adulterated within the meaning of 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm. In addition, our investigator found sanitation deficiencies in the growing room including heavy mold growth on the north wall, accumulation of rust and dust on overhead pipes, and dark stains on the inside of the irrigation tubes.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913 or via e-mail at lelrand@ora.fda.gov.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483 dated June 5, 2000
21 CFR PART 110
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement